1652

Docket No.: K21409USWO (C038435/0185656)

IN THE UNITED STATES PATENT AND TRADEMARK OFFICE

In re Application of:)

Tatsuo HOSHINO and Masako SHINJOH) Examiner: G. Raghu

Serial No.: 10/528,673) Art Unit: 1652

Filed: March 23, 2005)

For: **PROCESS FOR PRODUCING L-ASCORBIC ACID**

New York, New York
July 17, 2006

RESPONSE TO RESTRICTION REQUIREMENT

Mail Stop Amendment
Commissioner for Patents
P.O. Box 1450
Alexandria, VA 22313-1450

Sir:

This is in response to the Office Action mailed June 16, 2006, which set a one-month shortened statutory period for response. Accordingly, this response is filed timely upon mailing, with an executed certificate of mailing, on or before July 17, 2006 because July 16, 2006 fell on a Sunday. 37 CFR §§ 1.7 and 1.8. No fee is believed to be due. If it is determined that a fee is due, please charge such fee to Deposit Account No. 02-4467. A duplicate copy of this sheet is enclosed.

On page 2 of the Office Action, the Examiner issued a three-way restriction requirement pursuant to 35 USC §§ 121 and 372. The restriction divided the claims into the following allegedly distinct inventions: Group I (claims 1, 2, 5-8, 13, and

16) "drawn to a process for the production of L-ascorbic acid comprising: contacting an enzyme with a substrate selected from the group consisting of L-gulose, L-galactose, L-idose and L-talose or substrate is selected from the group consisting of L-gulono-1,4-lactone, L-gulonic acid, L-galactono-1,4-lactone, L-galactonic acid, L-idono-1,4-lactone, L-idonic acid, L-talono-1,4-lactone and L-talonic acid, wherein said enzyme has the amino acid sequence of SEQ ID NO:2;" Group II (claims 3, 9, 11, 14, and 17) "drawn to a process for the production of L-gulono-1,4-lactone or L-gulonic acid from L-gulose, wherein said enzyme has the amino acid sequence of SEQ ID NO:2, Enzyme B of *G. oxydans* DSM 4025;" and Group III (claims 4, 10, 12, 15, and 18) "drawn to a process for the production of L-galactono-1,4-lactone or L-galactonic acid from L-galactose, wherein said enzyme has the amino acid sequence of SEQ ID NO:2, Enzyme B of *G. oxydans* DSM 4025." (Paper No. 20060601 at 2-3).

For the reasons set forth below, the restriction requirement is respectfully traversed.

In making the restriction requirement, the Examiner asserted that "[t]he inventions listed as Groups I-III do not relate to a single general inventive concept under PCT Rule 13.1 because, under PCT Rule 13.2, they lack the same or corresponding special technical features." (*Id.* at 3). The Examiner further asserted that "[t]he special technical features linking the inventions of Group I-III appears to be that they all relate to a process of production of L-ascorbic acid or L-gulono-1,4-lactone or L-gulonic acid by contacting with an enzyme, wherein said enzyme has the amino acid sequence of SEQ ID NO: 2 or a process of production of L-ascorbic acid or L-gulono-1,4-lactone or

L-gulonic acid by contacting with an enzyme, wherein said enzyme is Enzyme B of *G. oxydans* DSM 4025." (*Id.*).

The Examiner relied on Asakura *et al.*, EP 0 832 974 A2 ("Asakura") for disclosing "the amino acid sequence of an enzyme from G. *oxydans* with alcohol and/or aldehyde dehydrogenase activity." (*Id.*). The Examiner further asserted that "L-gulonic acid is a known substrate for this enzyme" and "said enzyme has 100% sequence homology to SEQ ID NO: 2 of the instant application and therefore said enzyme can be used in the process for the production of L-gulonic acid or L-ascorbic acid." (*Id.*).

The Examiner then concluded that the groups were not joined by a special technical feature defined by PCT Rule 13.2 because "it does not define a contribution over the prior art." (*Id.*).

Contrary to the Examiner's position, it is respectfully submitted that Groups I-III do relate to a single general inventive concept and contain a special technical feature that makes a contribution over the prior art as required by PCT Rule 13.2.

PCT Rule 13.2 defines the manner in which unity of invention may be satisfied:

> Where a group of inventions is claimed in one and the same international application, the requirement of unity of invention referred to in Rule 13.1 shall be fulfilled only when there is a technical relationship among those inventions involving one or more of the same or corresponding special technical features. The expression "special technical features" shall mean **those technical features that define a contribution which each of the claimed inventions, considered as a whole, makes over the prior art**. (Emphasis added).

Asakura discloses "a recombinant enzyme preparation having an alcohol and/or aldehyde dehydrogenase activity which comprises one or more enzymatic polypeptide(s) selected from the group consisting of polypeptides which are identified by SEQ ID NO 5, SEQ ID NO 6, SEQ ID NO 7, and SEQ ID NO 8 ...." (Abstract). "[T]he AADHs provided ... can catalyze the oxidation of L-sorbose to 2KGA via L-sorbosone and/or the oxidation of D-sorbitol to L-sorbose. More particularly, the AADHs provided ... contain Enzyme A, Enzyme A', Enzyme A", and Enzyme B, which have the amino acid sequences shown in SEQ ID NO. 5, 6, 7, and 8, respectively." (Page 6, lines 5-10). Asakura further discloses at Table 1 the substrate specificities for Enzyme A, Enzyme A', Enzyme A", and Enzyme B using n-propanol, isopropanol, D-glucose, D-sorbitol, L-sorbosone, D-mannitol, L-sorbose, and D-fructose. (Page 7, lines 5-33).

Here, all the claims recite a process for the production of vitamin C or an intermediate thereof using an enzyme according to SEQ ID: 2 or Enzyme B of *G. oxydans* DSM 4025, where the substrate is selected from, for example, L-gulose and L-galactose. (*See* International Preliminary Examination Report for PCT/EP2003/010489, now U.S. Application Serial No. 10/528,673, at paragraph 2.1 discussing the novelty of the present invention over Asakura). Here too, the Examiner has failed to identify where there is a ***disclosure or suggestion*** of the use of L-gulose or L-galactose as a substrate for Enzyme B or, for that matter, Enzyme A, Enzyme A', or Enzyme A". At most, the Examiner relies on Asakura as disclosing the use of L-sorbosone as a substrate for the production of 2-KGA using Enzyme B. (*See* Table 1, Page 7). But, that is not what is recited in the present claims.

Accordingly, the rejection's use of Asakura cannot serve to nullify "unity of invention" under PCT Rules 13.1 and 13.2 because it fails to identify where in Asakura there is a ***disclosure of what is presently claimed***. For this reason, it is respectfully submitted that the restriction requirement has been rendered moot and should be withdrawn.

Although unnecessary in light of the foregoing, in accordance with restriction practice, the subject matter of claims 1, 2, 5-8, 13, and 16 (Group I) is hereby provisionally elected for prosecution, with traverse, to satisfy the requirements of 37 CFR § 1.143.

If the Examiner has any questions regarding this paper, please contact the undersigned attorney.

I hereby certify that this correspondence is being deposited with the United States Postal Service with sufficient postage as first class mail in an envelope addressed to: Mail Stop Amendment, Commissioner for Patents, P.O. Box 1450 Alexandria, VA 22313-1450, on July 17, 2006.

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Respectfully submitted,

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